Sun Pharmaceutical

Halol OAI: Limited impact, specialty drives outlook

Amey Chalke
amey.chalke@jmfl.com | Tel: (91 22) 66303056
Abin Benny
abin.benny@jmfl.com | Tel: (91 22) 69703621

We acknowledge the support of **Gourav Bhama** (gourav.bhama@jmfl.com) in preparation of this report.

On 9th Sep'25, the US FDA classified Sun Pharma's Halol facility as "Official Action Indicated" (OAI), following its June inspection that resulted in eight Form-483 observations around process and documentation gaps. The site, which has been under Import Alert since 2022, continues to supply only exempted products, and the OAI status indicates that this restriction is unlikely to ease in the near term. That said, Sun Pharma's reliance on US generics has reduced meaningfully— we estimate it to have reduced to 14% of operating revenue in FY25 from 24% in FY21—diminishing Halol's importance compared with 5-6 years ago. The company's growth outlook and stock performance are now more closely tied to its US and global specialty businesses, which remain the key drivers.

- **Historical context:** In Dec'22, Halol received an FDA Warning Letter for CGMP violations and was placed under Import Alert. Since then, the company has been working on Corrective and Preventive Actions (CAPA), but the OAI status shows gaps remain.
- **Jun'25 inspection:** From 2nd–13th Jun'25, the FDA inspected Halol and issued a Form-483 with eight observations. These highlighted lapses in processes, documentation, and aseptic practices. The OAI classification stems from these findings.
- **9th September update:** The US FDA has classified Sun Pharma's Halol facility as "Official Action Indicated" (OAI) after its June inspection, implying the site is not fully compliant with CGMP norms. The facility remains under Import Alert, blocking US shipments except for limited exemptions in case of drug shortages. This signals a continued regulatory hurdle for Sun Pharma despite prior corrective efforts.
- **Our understanding:** The Halol facility, which had already been placed under Import Alert earlier, continues to supply only exempted products, and the latest OAI classification indicates that this status is unlikely to change in the near term. Sun Pharma's dependence on the US generics business has steadily declined. We estimate it to have reduced to 14% of operating revenue in FY25 from 24% in FY21, thereby reducing Halol's importance compared to 5-6 years ago. For the company's growth prospects as well as stock performance, the US and global specialty businesses remain the key drivers.

APPENDIX I

JM Financial Institutional Securities Limited

Corporate Identity Number: U67100MH2017PLC296081
Member of BSE Ltd. and National Stock Exchange of India Ltd.
SEBI Registration Nos.: Stock Broker - INZ000163434, Research Analyst - INH000000610
Registered Office: 7th Floor, Cnergy, Appasaheb Marathe Marg, Prabhadevi, Mumbai 400 025, India.
Board: +91 22 6630 3030 | Fax: +91 22 6630 3488 | Email: jmfinancial.research@jmfl.com | www.jmfl.com
Compliance Officer: Mr. Sahil Salastekar | Tel: +91 22 6224 1743 | Email: sahil.salastekar@jmfl.com
Grievance officer: Mr. Sahil Salastekar | Tel: +91 22 6224 1743 | Email: instcompliance@jmfl.com

Investment in securities market are subject to market risks. Read all the related documents carefully before investing.

Definition of ratings	
Rating	Meaning
Buy	Total expected returns of more than 10% for stocks with market capitalisation in excess of INR 200 billion and REITs* and more than 15% for all other stocks, over the next twelve months. Total expected return includes dividend yields.
Hold	Price expected to move in the range of 10% downside to 10% upside from the current market price for stocks with market capitalisation in excess of INR 200 billion and REITs* and in the range of 10% downside to 15% upside from the current market price for all other stocks, over the next twelve months.
Sell	Price expected to move downwards by more than 10% from the current market price over the next twelve months.

* REITs refers to Real Estate Investment Trusts.

Research Analyst(s) Certification

The Research Analyst(s), with respect to each issuer and its securities covered by them in this research report, certify that:

All of the views expressed in this research report accurately reflect his or her or their personal views about all of the issuers and their securities; and

No part of his or her or their compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed in this research report.

Important Disclosures

This research report has been prepared by JM Financial Institutional Securities Limited (JM Financial Institutional Securities) to provide information about the company(ies) and sector(s), if any, covered in the report and may be distributed by it and/or its associates solely for the purpose of information of the select recipient of this report. This report and/or any part thereof, may not be duplicated in any form and/or reproduced or redistributed without the prior written consent of JM Financial Institutional Securities. This report has been prepared independent of the companies covered herein.

JM Financial Institutional Securities is registered with the Securities and Exchange Board of India (SEBI) as a Research Analyst and a Stock Broker having trading memberships of the BSE Ltd. (BSE) and National Stock Exchange of India Ltd. (NSE). No material disciplinary action has been taken by SEBI against JM Financial Institutional Securities in the past two financial years which may impact the investment decision making of the investor. Registration granted by SEBI and certification from the National Institute of Securities Market (NISM) in no way guarantee performance of JM Financial Institutional Securities or provide any assurance of returns to investors.

JM Financial Institutional Securities renders stock broking services primarily to institutional investors and provides the research services to its institutional clients/investors. JM Financial Institutional Securities and its associates are part of a multi-service, integrated investment banking, investment management, brokerage and financing group. JM Financial Institutional Securities and/or its associates might have provided or may provide services in respect of managing offerings of securities, corporate finance, investment banking, mergers & acquisitions, broking, financing or any other advisory services to the company(ies) covered herein. JM Financial Institutional Securities and/or its associates might have received during the past twelve months or may receive compensation from the company(ies) mentioned in this report for rendering any of the above services.

JM Financial Institutional Securities and/or its associates, their directors and employees may; (a) from time to time, have a long or short position in, and buy or sell the securities of the company(ies) mentioned herein or (b) be engaged in any other transaction involving such securities and earn brokerage or other compensation or act as a market maker in the financial instruments of the company(ies) covered under this report or (c) act as an advisor or lender/borrower to, or may have any financial interest in, such company(ies) or (d) considering the nature of business/activities that JM Financial Institutional Securities is engaged in, it may have potential conflict of interest at the time of publication of this report on the subject company(ies).

Neither JM Financial Institutional Securities nor its associates or the Research Analyst(s) named in this report or his/her relatives individually own one per cent or more securities of the company(ies) covered under this report, at the relevant date as specified in the SEBI (Research Analysts) Regulations, 2014.

The Research Analyst(s) principally responsible for the preparation of this research report and their immediate relatives are prohibited from buying or selling debt or equity securities, including but not limited to any option, right, warrant, future, long or short position issued by company(ies) covered under this report. The Research Analyst(s) principally responsible for the preparation of this research report or their immediate relatives (as defined under SEBI (Research Analysts) Regulations, 2014); (a) do not have any financial interest in the company(ies) covered under this report or (b) did not receive any compensation from the company(ies) covered under this report, or from any third party, in connection with this report or (c) do not have any other material conflict of interest at the time of publication of this report. Research Analyst(s) are not serving as an officer, director or employee of the company(ies) covered under this report.

While reasonable care has been taken in the preparation of this report, it does not purport to be a complete description of the securities, markets or developments referred to herein, and JM Financial Institutional Securities does not warrant its accuracy or completeness. JM Financial Institutional Securities may not be in any way responsible for any loss or damage that may arise to any person from any inadvertent error in the information contained in this report. This report is provided for information only and is not an investment advice and must not alone be taken as the basis for an investment decision.

This research report is based on the fundamental research/analysis conducted by the Research Analyst(s) named herein. Accordingly, this report has been prepared by studying/focusing on the fundamentals of the company(ies) covered in this report and other macro-economic factors. JM Financial Institutional Securities may have also issued or may issue, research reports and/or recommendations based on the technical/quantitative analysis of the company(ies) covered in this report by studying and using charts of the stock's price movement, trading volume and/or other volatility parameters. As a result, the views/recommendations expressed in such technical research reports could be inconsistent or even contrary to the views contained in this report.

The investment discussed or views expressed or recommendations/opinions given herein may not be suitable for all investors. The user assumes the entire risk of any use made of this information. The information contained herein may be changed without notice and JM Financial Institutional Securities reserves the right to make modifications and alterations to this statement as they may deem fit from time to time.

This report is neither an offer nor solicitation of an offer to buy and/or sell any securities mentioned herein and/or not an official confirmation of any transaction.

This report is not directed or intended for distribution to, or use by any person or entity who is a citizen or resident of or located in any locality, state, country or other jurisdiction, where such distribution, publication, availability or use would be contrary to law, regulation or which would subject JM Financial Institutional Securities and/or its affiliated company(ies) to any registration or licensing requirement within such jurisdiction. The securities described herein may or may not be eligible for sale in all jurisdictions or to a certain category of investors. Persons in whose possession this report may come, are required to inform themselves of and to observe such restrictions.

Additional disclosure only for U.S. persons: JM Financial Institutional Securities has entered into an agreement with JM Financial Securities, Inc. ("JM Financial Securities"), a U.S. registered broker-dealer and member of the Financial Industry Regulatory Authority ("FINRA") in order to conduct certain business in the United States in reliance on the exemption from U.S. broker-dealer registration provided by Rule 15a-6, promulgated under the U.S. Securities Exchange Act of 1934 (the "Exchange Act"), as amended, and as interpreted by the staff of the U.S. Securities and Exchange Commission ("SEC") (together "Rule 15a-6").

This research report is distributed in the United States by JM Financial Securities in compliance with Rule 15a-6, and as a "third party research report" for purposes of FINRA Rule 2241. In compliance with Rule 15a-6(a)(3) this research report is distributed only to "major U.S. institutional investors" as defined in Rule 15a-6 and is not intended for use by any person or entity that is not a major U.S. institutional investor. If you have received a copy of this research report and are not a major U.S. institutional investor, you are instructed not to read, rely on, or reproduce the contents hereof, and to destroy this research or return it to JM Financial Institutional Securities or to JM Financial Securities.

This research report is a product of JM Financial Institutional Securities, which is the employer of the research analyst(s) solely responsible for its content. The research analyst(s) preparing this research report is/are resident outside the United States and are not associated persons or employees of any U.S. registered broker-dealer. Therefore, the analyst(s) are not subject to supervision by a U.S. broker-dealer, or otherwise required to satisfy the regulatory licensing requirements of FINRA and may not be subject to the Rule 2241 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

Any U.S. person who is recipient of this report that wishes further information regarding, or to effect any transaction in, any of the securities discussed in this report, must contact, and deal directly through a U.S. registered representative affiliated with a broker-dealer registered with the SEC and a member of FINRA. In the U.S., JM Financial Institutional Securities has an affiliate, JM Financial Securities, Inc. located at 1325 Avenue of the Americas, 27th Floor, Office No. 2715, New York, New York 10019. Telephone +1 (332) 900 4958 which is registered with the SEC and is a member of FINRA and SIPC.

Additional disclosure only for U.K. persons: Neither JM Financial Institutional Securities nor any of its affiliates is authorised in the United Kingdom (U.K.) by the Financial Conduct Authority. As a result, this report is for distribution only to persons who (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the "Financial Promotion Order"), (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000) in connection with the matters to which this report relates may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This report is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this report relates is available only to relevant persons and will be engaged in only with relevant persons.

Additional disclosure only for Canadian persons: This report is not, and under no circumstances is to be construed as, an advertisement or a public offering of the securities described herein in Canada or any province or territory thereof. Under no circumstances is this report to be construed as an offer to sell securities or as a solicitation of an offer to buy securities in any jurisdiction of Canada. Any offer or sale of the securities described herein in Canada will be made only under an exemption from the requirements to file a prospectus with the relevant Canadian securities regulators and only by a dealer properly registered under applicable securities laws or, alternatively, pursuant to an exemption from the registration requirement in the relevant province or territory of Canada in which such offer or sale is made. This report is not, and under no circumstances is it to be construed as, a prospectus or an offering memorandum. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon these materials, the information contained herein or the merits of the securities described herein and any representation to the contrary is an offence. If you are located in Canada, this report has been made available to you based on your representation that you are an “accredited investor” as such term is defined in National Instrument 45-106 Prospectus Exemptions and a “permitted client” as such term is defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Under no circumstances is the information contained herein to be construed as investment advice in any province or territory of Canada nor should it be construed as being tailored to the needs of the recipient. Canadian recipients are advised that JM Financial Securities, Inc., JM Financial Institutional Securities Limited, their affiliates and authorized agents are not responsible for, nor do they accept, any liability whatsoever for any direct or consequential loss arising from any use of this research report or the information contained herein.